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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,767	10/17/2006	Lene Moller	13323-105002	9900

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
05/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/587,767	MOLLER, LENE	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,14-27,30-34 and 50-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12,14-27,30-34 and 50-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02.15.08; 09.03.08; 02.09.09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-33, to thrombin, in the reply filed on March 19, 2009 is acknowledged. The traversal is on the ground(s) that Ferdman et al. fail to explicitly refer to a gelatin or collagen powder having a mean particle size in the range of 30 to 250 μm. Therefore, the pending claims define a special technical feature over the prior art, and Groups I and II have unity of invention. Applicants respectfully request that the restriction requirement be withdrawn with respect to Groups I and II. Applicants' arguments have been fully considered and are believed to be persuasive. The restriction requirement with respect to Groups I and II is therefore withdrawn.

Claims 10-11, 13, 28-29, 35-49 are canceled. Claims 1-9, 12, 14-27, 30-34, 50-58 are currently under examination.

Priority: The request for priority to provisional applications 60/546972, filed February 24, 2004, and 60/540005, filed January 30, 2004, is acknowledged.

Information Disclosure Statement

The information disclosure statement filed February 15, 2008, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claims 1, 12, 27, 30, 31, 33, 34, 52 are objected to because of the following informalities: the term "gelatine" should be amended to "gelatin"; further in claim 32, line 2, the terms "according to" or "as defined in" should be inserted between "composition" and "claim 31". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 7, 15-17, 33, 51, 54, 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 54 recite "elongate tip". The term "elongate tip" is unclear. It appears that said terms should be amended to "elongated tip."

Regarding claims 7 and 58, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 15 recites said powder is a dry powder. It is unclear what is meant by "dry powder" since a powder is generally assumed to be inherently dry with 0% moisture. Therefore, it is unclear how the powder can also have at most 20% (w/w) moisture content if a "dry powder" since it is generally accepted that "dry" means having 0% moisture.

Claim 17, line 2, recites "poured density." It is unclear if by "poured density", Applicants mean "density." Further clarification is requested to distinguish the differences, if any, between "poured density" and "density."

Claim 33 is drawn to a method of making a composition comprising a dry gelatin or collagen powder; however, there is no active step of making said composition in the claim.

Claim 51, line 4, recites "derivatives." It is unclear what is meant by "derivatives" and which compounds and/or structures would be functionally equivalent to the agents listed in said claim 51.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Silver et al. (US 5196185). Silver et al. teach a composition of collagen powder having a particle size of from 0.1 to 50 μm (col. 4 lines 15-21; claims 30-31). In example I, Silver et al. also teach a method of preparing collagen powder having a particle size of 0.1 to 50 μm (col. 4 lines 15-21; claim 33). Silver et al. further teach a method of wound treatment comprising applying to a wound, the collagen powder composition in the form of an aerosol (col. 6 lines 30-45; claim 32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 12, 14-22, 25-27, 34, 50-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (US 5951531; IDS 02.15.08) in view of Silver et al. (US 5196185). Ferdman et al. disclose an apparatus for containing a chamber storing a composition comprising gelatin or collagen powder (abstract, col. 3 lines 6-25; claim 1, 25-26, 34). Ferdman et al. disclose a variety of hemostatic agents can be used with the apparatus, including collagen powder, where said hemostatic agent has a density of 0.016 to 0.064 g/cm^3 (col. 3 lines 15-20; claim 15-17, 27, 50). As noted in Figure 2, the apparatus has a source chamber (28) for containing the collagen powder (col. 3 lines 29-30; claim 6-7, 57-58). The apparatus is a spraying device which is hand-held and is activated by a hand-pushed button (col. 4 lines 17-24; claim 4-5, 55-56). The hemostatic agent is dispersed through the outlet conduit (80) and onto living tissue, wherein the outlet conduit has a diameter of about 0.5 cm (col. 5 lines 1-5, col. 6 lines 15-20; claim 2, 53). Ferdman et al. disclose that the opening (108) is configured for receiving a slidable valve gate (110), where the valve gate (110) controllably discharges collagen powder from said apparatus (col. 5 lines 50-55; claim 8-9, 34). From Figure 3, the outlet conduit (80) has an elongate tip (Fig. 3; claim 3, 54). Ferdman et al. do not teach said collagen powder has a mean particle size, i.e. of 30 to 250 μm.

As noted above, Silver et al. teach collagen powder having a particle size of from 0.1 to 50 μm can be applied onto a wound (col. 4 lines 15-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Ferdman et al. by substituting the collagen powder having a particle size of 0.1-50 μm of Silver et al. for the collagen powder used in Ferdman et al. (claims 1-9, 14-17, 25-27, 34, 50, 53-58). The motivation to do so is given by Silver et al. which disclose that said collagen powder can be used for the treatment of a wound and Ferdman et al. which disclose that collagen powder can be used in an apparatus for treating tissue; therefore, it would be reasonable for one of ordinary skill to know that any suitable collagen powder that can be used to treat wounds, regardless of particle size, can be successfully incorporated into said apparatus of Ferdman et al. since the healing properties of the collagen powder would be the same.

Regarding the limitation of claims 8-9, 34, i.e. the protective structure is a skirt portion arranged to extend from the discharge opening, it would be reasonable for one of ordinary skill to recognize that the sliding valve gate of Ferdman et al. is a protective structure that is equivalent to a skirt portion that extends from the discharge opening since both structures function to control the discharge of the hemostatic agent.

Regarding the moisture content limitation that is recited in claims 16, 50, it should be noted that Ferdman et al. in view of Silver et al. disclose collagen powder; therefore, it would be reasonable for one of ordinary skill to conclude that the powder by inherency would be dry and have no moisture content.

Ferdman et al. also disclose that hemostatic agents can include dried gelatin (col. 3 lines 10-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the teachings of Ferdman et al. in view of Silver et al. as noted above by adding gelatin powder to the collagen powder of Ferdman et al. in view of Silver et al. (claims 12, 52). As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art." In this instance, Ferdman et al. disclose that dried gelatin and collagen powder are hemostatic agents; therefore, it would be reasonable for one of ordinary skill to combine two hemostatic agents in order to produce a third composition.

In addition to dried gelatin, Ferdman et al. also disclose polysaccharide and cellulose are appropriate hemostatic agents (col. 3 lines 10-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the teachings of Ferdman et al. in view of Silver et al. as noted above by adding an agent which improves the adhesive properties of the collagen powder, i.e. starch, glucose, etc. (claims 18-22, 51). As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art." In this instance, Ferdman et al. disclose that polysaccharide

is a hemostatic agent; therefore, it would be reasonable for one of ordinary skill to recognize that (poly)saccharides are hemostatic agents that can be combined with another known hemostatic agent to form a third composition.

While Ferdman et al. may not disclose the (poly)saccharide improves the adhesive properties of a collagen powder composition, it should be noted that "[I]t is not necessary in order to establish a prima facie case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from the prior art that the claimed compound or composition will have the same or a similar utility as one newly discovered by applicant"); In re Lintner, 458 F.2d 1013, 1018, 173 USPQ 560, 562 (CCPA 1972) ("The fact that [applicant] uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be prima facie obvious from the purpose disclosed in the references."). In this instance, the saccharide is being incorporated as a hemostatic agent with a known hemostatic agent, i.e. collagen powder, in order to arrive at a third composition comprising hemostatic agents.

Regarding the concentration of said agent recited in claim 22, it should be noted that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of

percentage ranges is the optimum combination of percentages."). In this instance, it would be reasonable for one of ordinary skill to determine at which concentration of polysaccharide would yield the optimum hemostatic composition for wound treatment.

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (US 5951531; IDS 02.15.08) in view of Silver et al. (US 5196185) in view of Epstein et al. (US 6045570; IDS 02.15.08). The teachings of Ferdman et al. in view of Silver et al. are outlined above. Ferdman et al. in view of Silver et al. do not teach thrombin.

Epstein et al. disclose thrombin can be mixed with collagen powder in order to form a biological sealant composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Ferdman et al. in view of Silver et al. by adding the thrombin of Epstein et al. to said collagen powder of Ferdman et al. in view of Silver et al. (claims 23-24). The motivation to do so is given by Epstein et al., which disclose that the addition of thrombin to collagen powder can form a biological sealant; therefore, it would be reasonable for one of ordinary skill to know that treating a wound with a biological sealant would improve healing of the wound.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

May 20, 2009